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DEPARTMENT OF STATE

[PUBLIC NOTICE: 10789]

Notice and Request for Comments on the Implications of Access and Benefit-Sharing (ABS) Regimes on Global Health and Biomedical Research

AGENCY: Department of State.

SUMMARY: In order to inform U.S. Government policy and international engagement, the U.S. Department of State (DOS) invites submission of comments from the public, academia, relevant industries, and other interested stakeholders on the implications of Access and Benefit-Sharing (ABS) regimes on global health and biomedical research. In particular, DOS invites comments related to the effects of Nagoya Protocol and other ABS implementation on public health systems. The Department will hold at least two public meetings to discuss these issues, on June 25 and September 20, 2019. Any future Meetings will be announced at <https://www.state.gov/bureaus-offices/under-secretary-for-economic-growth-energy-and-the-environment/bureau-of-oceans-and-international-environmental-and-scientific-affairs/office-of-international-health-and-biodefense/>

DATES: Written comments are welcome before each of the two planned public meetings referenced above and will be reviewed periodically beginning [INSERT DATE 30 DAYS AFTER PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: One submission per meeting is welcome, with no more than 10 pages of single-spaced text including relevant examples with no more than one page per example. Submissions should be made via the Internet at www.regulations.gov docket number DOS-2019-0016. For alternatives to online submissions, please contact Dr. Jennifer

Seedorff at (202) 647-3017 or seedorffje@state.gov. Note that relevant comments submitted to [regulations.gov](https://www.regulations.gov) will be posted without editing and will be available to the public; therefore, business-confidential information should be clearly identified as such and submitted by email. The public is strongly encouraged to file submissions electronically rather than by facsimile or mail.

FOR FURTHER INFORMATION CONTACT: Questions regarding the submission of comments should be directed to Dr. Jennifer Seedorff (202) 647-3017, seedorffje@state.gov.

SUPPLEMENTARY INFORMATION: Representatives from the Department of State will review written submissions and share them, as appropriate, with staff from other Federal Agencies to inform U.S. Government policy and our international engagements on these issues. U.S. officials may contact individuals making submissions for further information or explanation. In particular, we seek comments on and specific examples of the impacts of other countries' implementation of the Nagoya Protocol or other ABS measures on such issues as: international research collaborations, international pathogen sample sharing, infectious disease research, including influenza, Zika and other diseases, pandemic and epidemic preparedness and response, medical countermeasure product development efforts, investor interest in vaccine development, and other aspects. We would also welcome views on what the World Health Organization (WHO), other UN bodies, and non-governmental organizations can do to effectively protect public health equities in the context of the Nagoya Protocol and other national level ABS implementation. We also welcome examples of:

- 1) Monetary or non-monetary benefits to the global public health system that are facilitated by international sharing of pathogens, biospecimens, pathogen genetic sequence data, and/or relevant metadata.
- 2) Influenza-specific issues and/or examples related to the items described above or other items that could affect global influenza pandemic preparedness and response or efforts to combat seasonal influenza.
- 3) Non-ABS challenges and barriers with sharing pathogens internationally or that otherwise have significant implications for global pandemic or epidemic preparedness and response efforts that might merit additional attention or analysis.

Background: Biological threats to the U.S. homeland — whether as the result of deliberate attack, accident, or a natural outbreak — are growing and require actions to address them at their source. Naturally emerging outbreaks of viruses such as Ebola and Severe Acute Respiratory Syndrome (SARS), as well as the deliberate 2001 anthrax attacks in the United States, demonstrated the impact of biological threats on national security by taking lives, generating economic losses, and contributing to a loss of confidence in government institutions. To effectively prepare for or respond to epidemic and pandemic infectious disease threats, the United States government and other public health actors need rapid, systematic, and consistent access to both information and samples from outbreaks, including pathogens, related clinical material, pathogen genetic sequence data, epidemiological data, and relevant metadata. The Global Influenza Surveillance and Response System and Pandemic Influenza Preparedness Framework facilitate the sharing of samples of influenza viruses and access to vaccines and other benefits. WHO is engaging with Member States, stakeholders, and other UN bodies to

better understand the impacts of Nagoya Protocol and other ABS measures on public health, including the sharing of influenza and non-influenza pathogens.

Several meetings are planned in association with this request for written submissions.

Time and Date: Two initial meetings are planned on Tuesday, June 25 and Friday, September 20, 2019. Each meeting will begin at 1:30 p.m. EDT and last for up to two hours. If the Department decides to hold additional public meetings, the time and place will be announced on the Department website: <https://www.state.gov/bureaus-offices/under-secretary-for-economic-growth-energy-and-the-environment/bureau-of-oceans-and-international-environmental-and-scientific-affairs/office-of-international-health-and-biodefense/>

Place: The two initial meetings will be held at the U.S. State Department's Harry S. Truman Building, 2201 C Street NW, Washington, DC 20520. Please use the 21st Street entrance, and plan to arrive at least twenty minutes prior to the start of the meeting to allow for ID verification and escorting requirements.

Status: The meetings will be open to the public. Persons planning on attending must provide their full name and organization to Dr. Jennifer Seedorff at seedorffje@state.gov and copy RSVP-IHB@state.gov at least three days prior to each meeting. Persons who need special accommodations should also contact Dr. Seedorff at seedorffje@state.gov or (202) 647-3017 and copy RSVP-IHB@state.gov at least seven days before each meeting. Requests made after that time will be considered, but might not be possible to accommodate. Personal data is requested pursuant to Public Law 99-399 (Omnibus Diplomatic Security and Antiterrorism Act of 1986), as amended; Public Law 107-56

(USA PATRIOT Act); and E.O. 13356. The purpose of the collection is to validate the identity of individuals who enter 1033 Department facilities. The data will be entered into the Visitor Access Control System (VACS-D) database. Please see the Security Records System of Records Notice (State-36) at <http://www.state.gov/documents/organization/242611.pdf> for additional information.

Dated June 4, 2019.

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Bureau of Oceans and International Environmental and Scientific Affairs,

Department of State.

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